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Appl. No.: 10/570,124

Amdt. Dated February 17, 2009

Response to Office Action Mailed December 1, 2008

**REMARKS:** 

Applicant requests reconsideration and withdrawal of the pending rejections of the

claims, for the following reasons.

First, it is respectfully submitted that the examiner has failed to establish a prima 1.

facie case of obviousness, in view of the fact that critical portions of the rejection of claim 1 are

garbled and grammatically incorrect, with the result that the meaning of the rejection cannot be

discerned without engaging in conjecture and surmise as to its contents. Specifically, the Office

action at page 3, lines 8-17, states:

It would further have been obvious to modify the needle guide to allow the needle

to protrude slightly on the ampoule side to allow piercing of the ampoule instead

of making the ampoule Pickhard in view of van der Wal lacks locking members.

Curie et al. discloses snap-lock locking members on an interior wall coinciding

with snap locking members on a needle guide (column 2, lines 20-26). It would

have been obvious to modify Pickhard in view of van der Wal with locking

members on the sleeve coupled with locking members on the ampoule as taught

by Curie et al. It would have further been obvious that the interior of a barrel

form Curie et al. would be modified to the sleeve (12) of Pickhard in view of van

der Wal as described in van der Wal.

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Applicant is not absolutely sure how the teachings of the cited references are meant to be combined by the examiner in the passage above. It is respectfully submitted that the rejection is not understandable, and must be withdrawn and rephrased if it is to be relied upon to establish a prima facie case of obviousness.

2. Second, to the extent that the Applicant engages in conjecture to discern the meaning of the obviousness rejection of claim 1, it seems that the following argument would pertain. There has been no prima facie case of obviousness established because the cited references fail to disclose the features as claimed, and thus their combination would not have been obvious to those skilled in the art. Pickhard teaches an injection device in which the ampoule and the injection needle are arranged so that they are relatively displaceable to one other, so as to enable the separation of the injection needle and the ampoule from each other prior to use, and to establish fluid connection between the injection needle and the liquid to be injected inside the ampoule when needed.

In contrast to the teaching of Pickhard, the present invention as defined in claim 1 provides for a sleeve, in which the ampoule can be axially displaced. A plurality of radially inwardly protruding projections is formed on an inner periphery of the sleeve. These projections serve to restrict unintentional sliding of the ampoule inside the sleeve. The sleeve also comprises locking members cooperating with locking members of a needle guide. Release of the locking members is caused when the ampoule slides forward inside the sleeve, thereby releasing the needle guide from the sleeve and enabling the needle guide to slide forward to deploy the needle to its active position outside the housing of the injection device.

It could possibly be assumed from the present language of the rejection that the examiner is of the opinion that "member 12" of the injection device according to van der Wal is a sleeve, corresponding to the sleeve as taught by the present invention. This is, however, not true since member 12 of van der Wal is not a sleeve, but a "cartridge holder 12" (see van der Wal, col. 5,

line 41 and FIGS. 1-2), which comprises two concentric sleeve-like portions, a first portion 21 accommodating the cartridge and a second wider portion 29 slidably telescoping within an outer sleeve of the injection device. This structure can by no means be compared to the sleeve of claim 1, which is fixed within the second housing part. The fact that, in the van der Wal reference, the ampoule or the cartridge is arranged in some kind of tube shaped member cannot support an interpretation as apparently intended by the examiner without departing from a technically correct interpretation of the wording of instant claim 1. The sleeve of the present invention features various characteristics, such as the sleeve being fixed within the second housing part, and the sleeve comprising locking members that cooperate with locking members of a needle guide, so that it is quite clear that the cartridge holder 12 of van der Wal is a completely different structure. Thus, a combination of the sleeve as taught by Pickhard with the projections inside the cartridge holder of van der Wal would not have been obvious to a person skilled in the art.

In order to find obviousness to combine other features of claim 1 of present invention, the examiner also suggests combining a further reference (Curie et al.) with the combination discussed above. According to the examiner, Curie et al. discloses snap locking members on an interior wall coinciding with snap locking members on a needle guide. The cited passage (column 2, lines 20-26) of Curie et al., however, is not about a needle guide, but about a needle mount. This is consistent with the fact that in Curie et al. there is envisaged no displacement whatsoever of the needle mount, since this member is not axially displaceable like the needle guide according to claim 1 herein. According to column 5, lines 16-17 of Curie et al., the needle mount is fixed at the end of the barrel of a simple syringe. It is unclear how a simple snap lock at the tip of a conventional syringe can be compared to a snap lock on a slidable needle guide. It cannot be seen how a modification as suggested by the examiner on page 3, lines 13-15 could in any way lead to the device of instant claim 1, since coupling with locking members on the sleeve with locking members on the ampoule as taught by Curie et al. would not in any way engage the

needle guide to the sleeve or provide for a possibility to release the needle guide from the sleeve upon displacement of the ampoule inside the sleeve.

In view of the above it remains unclear how a combination of the cited documents would have been obvious to a person skilled in the art or could, even if the teachings of these documents where combined, yield a device as taught by the instant application.

It is respectfully submitted that the rejections fail to establish a prima facie case of obviousness, and further, to the extent that the meaning of the rejection can be discerned, the it is submitted that the rejection appears to rely upon a relatively arbitrary combination of mere words taken from prior art references; in some cases, the words actually refer to completely different members of injection devices that work in a completely different way.

In view of the arguments above, it is submitted that the rejections all should be withdrawn upon reconsideration.

Conclusion. It is respectfully submitted that the application is in condition for prompt allowance and that all of the objections, rejections and requirements raised in the Office action have been met or overcome. Early, favorable treatment of this application is requested.

The examiner is encouraged to telephone the undersigned with any questions or comments so that efforts may be made to resolve any remaining issues.

Extension Request and Deposit Account Charge Authorization. The Commissioner is hereby authorized to charge any and all required fees, or credit any overpayment, associated with this communication, including fees for any necessary extension of time under 37 CFR §1.136(a) for filing this communication, which extension is hereby requested, to our Deposit Account No. 50-0305 of Chapman and Cutler LLP.

Respectfully submitted.

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## CERTIFICATE OF FACSIMILE TRANSMISSION UNDER 37 C.F.R. § 1.8

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I hereby certify that the attached correspondence, namely: Response to Office Action, with deposit account fee charge authorization, was transmitted by facsimile on the date listed above, to the U.S. Patent Office at the facsimile number listed above, under 37 C.F.R. § 1.8.

<u>Signature:</u>

Typed Name of Person Signing this Certificate: Robert J. Schneider, Reg. No. 27,383

Date of Signature:

February 17, 2009